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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,014	08/21/2003	Douglas A. Devens JR.	10527-396001	6225

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FISH & RICHARDSON PC
P.O. BOX 1022
MINNEAPOLIS, MN 55440-1022

EXAMINER

MENDEZ, MANUEL A

ART UNIT PAPER NUMBER

3763

DATE MAILED: 10/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/645,014	Applicant(s) DEVENS, DOUGLAS A.	
	Examiner Manuel Mendez	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23, 25 and 26 is/are pending in the application.
- 4a) Of the above claim(s) 23, 25 and 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>11/31/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Claims 23, 25, and 26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on June 10, 2005.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Engelson et al., in view of Mortier et al., U.S. Patent No. 5,730,733**. The Engelson et al., patent discloses a catheter having **2 coextruded layers** comprising a first material and a second material having a different stiffness than a stiffness of the first material, wherein at least one of the layers varies in thickness axially along the device. The Engelson et al., patent does not disclose a catheter design having exactly four coextruded layers. However, the duplication of a well-known element of an apparatus, such as a layer, should not provide patentable weight to the claim. Moreover, as previously mentioned before, catheter designs having 4 layers are well known in the art as evidenced by the teachings of **Mortier et al., U.S. Patent No. 5,730,733**. As the applicant correctly states in the remarks, (1) Mortier et al., does indicate that multiple

Art Unit: 3763

layers can be coextruded, and (2) in figures 10b and 10c, Mortier et al., shows a multi-layered catheter (110) having four layers.

Based on the above observations, for a person of ordinary skill in the art, modifying the catheter design disclosed by Engelson et al., with additional layers including a 4 layer design as taught by Mortier et al., would have been considered obvious in view of the conventionality of the 4 layer embodiment.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Skribiski in view of Engelson et al., and Mortier et al., U.S. Patent No. 5,730,733.**

Skribiski discloses a first layer, a second layer, the second layer being coextruded with the first layer, and a third layer comprising an adhesive material between the first and second layers. Skribiski does not disclose variations in thickness along an axial portion of the device. However, catheter designs having variations in thickness are conventional in the art.

The Engelson et al., patent discloses a catheter having **2 coextruded layers** comprising a first material and a second material having a different stiffness than a

Art Unit: 3763

stiffness of the first material, wherein at least one of the layers varies in thickness axially along the device.

Based on the above observations, for a person of ordinary skill in the art, modifying the Skribiski patent with layers that vary in thickness, as taught by Engelson, et al., would have been considered obvious because changes in the thickness of the layers would have resulted in respective changes to the flexibility of the catheter.

Claim Rejections - 35 USC § 103

Claims 2-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Engelson et al.**, in view of **Mortier et al.**, and in further view of **Fanselow et al.**, and **Chin et al.** Neither Engelson et al., or Mortier et al., discloses a catheter having 5, 7, or 13 layers. However, the Fanselow et al., patent shows that designing catheters having 4 or 5 layers is conventional in the art. Similarly, Chin et al., demonstrates the conventionality of designing catheters having 7 layers.

Accordingly, based on the teachings of Fanselow et al., and Chin et al., for a person of ordinary skill in the art, it would have been considered obvious to modify the catheter design disclosed by Engelson et al., as shown in figures 10a-10c, with additional layers (5, 7, or 13 layers). Conclusively, since multiple layer catheter designs are conventional in the art, increasing or duplicating the number of layers in a catheter would have been considered obvious in view of the conventionality of said catheter enhancements.

Response to Arguments

Applicant's arguments with respect to claims 1-22 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

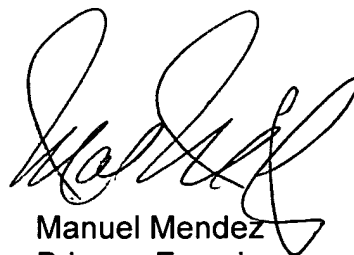
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manuel Mendez whose telephone number is 703-272-4977. The examiner can normally be reached on 0730-1800 hrs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Nicholas D. Lucchesi can be reached on 571-272-4977. The fax phone

Art Unit: 3763

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Manuel Mendez', is positioned above the printed name and title.

Manuel Mendez
Primary Examiner
Art Unit 3763